

claims

1. Method for the detection of an analyte in a sample comprising the steps:
- (a) providing a solid phase which comprises a non-porous support and at least two spatially separate test areas, the test areas each containing different immobilized analyte-specific receptors,
 - (b) contacting the sample with the solid phase and with at least one free analyte-specific receptor which carries a signal generating group or is capable of binding to a signal generating group, and
 - (c) detecting the presence or/and the amount of the analyte by determining the signal generating group on the test areas.
2. Method as claimed in claim 1,
wherein
the analyte to be detected is a homogeneous or heterogeneous population.
3. Method as claimed in claim 1 or 2,
wherein
the analyte is a heterogeneous antibody population, an antigen mixture or a mixture of antigens and antibodies that may be different.
4. Method as claimed in one of the previous claims,
wherein
the test areas have a diameter of 0.01 to 1 mm.

5. Method as claimed in one of the previous claims,
wherein
the solid phase is prepared by the separate, direct specific application of the different analyte-specific receptors on the spatially separate test areas.
6. Method as claimed in one of the previous claims,
wherein
the coating on the test areas is in each case composed of a single type of binding molecule.
7. Method as claimed in one of the previous claims,
wherein
a solid phase is used which additionally comprises at least one control area which contains no analyte-specific receptor.
8. Method as claimed in one of the previous claims,
wherein
a universal detection reagent and in particular labelled latex particles are used to detect complexes formed from the analyte and reagents that bind thereto.
9. Solid phase for the detection of an analyte in a sample,
wherein
it comprises a non-porous support and at least two spatially separate test areas, the test areas each containing different reagents which bind specifically to the analyte to be determined.

10. Solid phase as claimed in claim 9,
wherein
the test areas each contain different reagents
which bind to different epitopes or/and subtypes of
the analyte or/and to different analyte types.
11. Solid phase as claimed in claim 9 or 10,
wherein
the non-porous support is made of polystyrene.
12. Solid phase as claimed in one of the claims 9 to
11,
wherein
the test areas have a diameter of 0.01 to 1 mm.
13. Use of a solid phase as claimed in one of the
claims 9 to 12 in an immunoassay.
14. Test kit for the detection of an analyte in a
sample comprising a solid phase as claimed in one
of the claims 9 to 12 as well as labelled detection
reagents.
15. Test kit as claimed in claim 14,
wherein
it contains labelled latex particles as the
universal detection reagent.
16. Method for the simultaneous determination of an
antigen and of an antibody that is specifically
directed against this antigen in a sample
comprising the steps:
(a) providing a solid phase on which an immobilized

- X
- receptor that can bind to the antigen to be determined is applied in a first test area and an immobilized receptor that can bind to the antibody to be determined is applied in a second test area which is spatially separated therefrom,
- (b) contacting the sample with the solid phase and with a free analyte-specific receptor which carries a signal generating group or is capable of binding to a signal generating group and
- (c) detecting the presence or/and the amount of the antigen and of the antibody by determining the signal generating group on the solid phase.
17. Method as claimed in claim 16,
wherein
the antigen is detected using a sandwich test.
18. Method as claimed in one of the claims 16 or 17,
wherein
the antibody is detected using a back titration method.
19. Method as claimed in claim 16 or 17,
wherein
the antibody is detected using a bridge method.
20. Method as claimed in one of the claims 16 or 17,
wherein
the antibody is detected using an indirect test format.

05220005-163260

21. Method as claimed in one of the claims 16 to 20,
wherein
the coating of the first test area capable of
binding is formed from immobilized antibodies which
are specific for an epitope of the antigen to be
detected.
22. Method as claimed in claim 21,
wherein
antibodies which are specific for different
subtypes of the antigen to be detected, are applied
in separate test areas.
23. Method as claimed in claim 21 or 22,
wherein
the antibody is selected from viral antibodies, in
particular anti-HIV I antibodies, anti-HIV II
antibodies, anti-HBV antibodies and anti-HCV
antibodies.
24. Method as claimed in one of the claims 16 to 23,
wherein
the coating of the second test area capable of
binding is composed of antigens which are specific
for the antibodies to be detected.
25. Method as claimed in claim 24,
wherein
the antigens are selected from the group comprising
HIV I, HIV II, HBV and HCV.

26. Method as claimed in one of the claims 16 to 25,
wherein
the antigen to be determined is HIV p24 and the
antibody to be determined is anti-p24.
27. Method as claimed in one of the claims 16 to 26,
wherein
a non-porous solid phase is used.
28. Method as claimed in one of the claims 16 to 27,
wherein
the detection is carried out using labelled
antibodies which are directed against the analyte.
29. Method as claimed in claim 28,
wherein
the label is selected from fluorescent groups,
chemiluminescent groups, radioactive labels, enzyme
labels, coloured labels and sol particles.
30. Method as claimed in one of the claims 16 to 29,
wherein
the detection is carried out using a universal
detection reagent in particular labelled latex
particles.
31. Method as claimed in one of the claims 16 to 30,
wherein
the solid phase is prepared by direct, separate
application of the specific coatings capable of
binding to the individual test areas.

03/2008-AE/000

32. Method as claimed in one of the claims 16 to 31,
wherein
the coating on the test areas is in each case composed of a single type of molecule that is capable of binding.
33. Solid phase for the simultaneous determination of an antigen and of an antibody directed specifically against this antigen in a sample comprising at least a first test area and at least a second test area,
wherein
the first test area has a coating that can bind specifically to an antigen and the second test area has a coating which can bind specifically with an antibody directed against the antigen.
34. Solid phase as claimed in claim 33,
wherein
the coatings are homogeneous and each contains only a single type of reagent that is capable of binding.
35. Solid phase as claimed in claim 33 or 34,
wherein
the test areas are applied on a non-porous support.
36. Solid phase as claimed in claim 35,
wherein
the non-porous support is made of polystyrene.

37. Solid phase as claimed in one of the claims 33 to 36,
wherein
the individual test areas have a diameter of 0.01 to 1 mm.
38. Use of a solid phase as claimed in one of the claims 33 to 37 in an immunoassay for the simultaneous detection of an antigen and of an antibody directed specifically against this antigen.
39. Test kit for the simultaneous determination of an antigen and of an antibody directed specifically against this antigen comprising a solid phase as claimed in one of the claims 33 to 37 and labelled detection reagents.
40. Test kit as claimed in claim 39,
wherein
it contains a universal detection reagent.
41. Method for the detection of an analyte in a sample comprising the steps:
(a) providing a solid phase which comprises a support and at least two spatially separate test areas, the test areas each containing different immobilized analyte-specific receptors,
(b) contacting the sample with the solid phase and with at least one free analyte-specific receptor which carries a signal generating group or is capable of binding to a signal generating group, and

- (c) detecting the presence or/and the amount of the analyte by determining the signal generating group on the test areas whereby a signal is classified as positive that is above a predetermined test-area-specific threshold value and is classified as negative when it is below a predetermined test-area-specific threshold value.
42. Method as claimed in claim 41,
wherein
the cut-off values are each determined individually for a test area.
43. Method as claimed in claim 41 or 42,
wherein
the cut-off values are set differently for at least 2 test areas.

XPS
AI